# PATENT COOPERATION TREATY

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

Martin Jean-Jacques [stamp]
Cabinet Regimbeau
20, Rue de Chazelles
75847 Paris Cedex 17
FRANCE

# PCT

## NOTIFICATION OF TRANSMITTAL OF INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Rule 71.1)

| | |
|---|---|
| | Date of mailing *(day/month/year)*<br>25.05.2001 |
| Applicant's or agent's file reference<br>340623/18441 | IMPORTANT NOTIFICATION |

| International application No. | International filing date *(day/month/year)* | Priority date *(day/month/year)* |
|---|---|---|
| PCT/FR00/00394 | 17/02/2000 | 17/02/1999 |

Applicant
PIERRE FABRE MEDICAMENT et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.

2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.

3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.

4. REMINDER

   The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

   Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the International preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

   For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

| **Name and mailing address of the IPEA/** | Authorized officer: |
|---|---|
| European Patent Office<br>D-80298 Munich<br>Tel. (+ 49-89) 2399-0, Tx: 523656 epmu d<br>Fax: (+ 49-89) 2399-4465 | Neumann, M<br><br>Tel. +49 89 2399-7351 |

Form PCT/IPEA/416 (July 1992)

09/913107

Translation

RECEIVED
MAR 04 2002
TECH CENTER 1600/2900

# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

| Applicant's or agent's file reference<br>340623/18441 | **FOR FURTHER ACTION** | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
|---|---|---|
| International application No.<br>PCT/FR00/00394 | International filing date (*day/month/year*)<br>17 February 2000 (17.02.00) | Priority date (*day/month/year*)<br>17 February 1999 (17.02.99) |
| International Patent Classification (IPC) or national classification and IPC<br>A61K 39/00 | | |
| Applicant<br>PIERRE FABRE MEDICAMENT | | |

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 8 sheets, including this cover sheet.

☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of _____ sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☒ Certain defects in the international application
- VIII ☒ Certain observations on the international application

| Date of submission of the demand | Date of completion of this report |
|---|---|
| 11 September 2000 (11.09.00) | 25 May 2001 (25.05.2001) |
| Name and mailing address of the IPEA/EP<br><br>Facsimile No. | Authorized officer<br><br>Telephone No. |

# INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/FR00/00394

## I. Basis of the report

1. With regard to the **elements** of the international application:*

☐ the international application as originally filed

☒ the description:

pages 1-20, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the claims:

pages 1-24, as originally filed

pages _____, as amended (together with any statement under Article 19

pages _____, filed with the demand

pages _____, filed with the letter of _____

☒ the drawings:

pages 1/2-2/2, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

☐ the sequence listing part of the description:

pages _____, as originally filed

pages _____, filed with the demand

pages _____, filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

☐ the language of publication of the international application (under Rule 48.3(b)).

☐ the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☒ furnished subsequently to this Authority in written form.

☒ furnished subsequently to this Authority in computer readable form.

☒ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☒ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. ☐ The amendments have resulted in the cancellation of:

☐ the description, pages _____

☐ the claims, Nos. _____

☐ the drawings, sheets/fig _____

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* *Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rule 70.16 and 70.17).*

** *Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application.

☒ claims Nos. 1-16

because:

☒ the said international application, or the said claims Nos. 1-16 relate to the following subject matter which does not require an international preliminary examination *(specify)*:

See separate sheet.

☒ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. 17 are so unclear that no meaningful opinion could be formed *(specify)*:

See separate sheet.

☐ the claims, or said claims Nos. _____ are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for said claims Nos. _____ .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

**Supplemental Box**
(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of: III.

1. The present Authority considers that the subject matter of claims 1-16 is covered by the provisions of PCT Rule 67.1(iv). For this reason, no opinion will be given on the question of whether the subject matter of these claims is industrially applicable (PCT Article 34(4)(a)(i)).

2. The subject matter of claim 17 has not been clearly defined because it does not include technical features. For this reason, it is not possible to form a meaningful opinion regarding the novelty and inventive step of this claim.

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

1. Statement

| | | | |
|---|---|---|---|
| Novelty (N) | Claims | 1-16, 18-24 | YES |
| | Claims | | NO |
| Inventive step (IS) | Claims | 1-16, 18-24 | YES |
| | Claims | | NO |
| Industrial applicability (IA) | Claims | 18-24 | YES |
| | Claims | | NO |

2. Citations and explanations

The following documents cited in the search report are mentioned in the present written opinion. The numbering given below will be used throughout the rest of the procedure:

D1: JOURNAL OF IMMUNOLOGY, vol. 160, no. 4, 1998, pages 1750-1758
D2: EUROPEAN JOURNAL OF BIOCHEMISTRY, vol. 255, 1998, pages 446-454
D3: RESEARCH IN IMMUNOLOGY, vol. 149, no. 1, 1998, page 99

Document D4 is not cited in the international search report. A copy of the abstract of this document is attached:

D4: IMMUNOLOGICAL REVIEW, vol. 146, 1995, pages 57-79

1. Novelty

The subject matter of **claims 1-16 and 18-24** is considered to be **novel** (PCT Article 33(2)) because none of the documents cited in the search report

discloses the combined use of an OmpA protein and a peptide having sequence SEQ ID NO 3 ELAGIGILTV.

2. Inventive step

2.1 Document D1, which is considered to be the closest prior art, describes the use of the peptide antigen having the sequence ELAGIGILTV (page 1752, table no. 2) to generate a cytotoxic T cell response directed against melanoma cells (page 1757, right-hand column, paragraph 2). The peptide can be attached to HLA-A*0201 (abstract). Said peptide could be used as a pharmaceutical preparation (vaccine) for causing strong anti-tumour CTL responses (page 1757, right-hand column, paragraph 2).
Therefore, a vaccine has been theoretically suggested but not produced.

The subject matter of independent claims 1 and 19 differs from D1 in that the peptide described above is associated with a protein (OmpA) when it is used for preparing a pharmaceutical composition for generating a cytotoxic T cell response directed against melanoma cells.

The effect of the presence of protein OmpA is such that it causes a strong CTL response directed against melanoma cells.

The problem that the present invention is intended to solve can thus be considered to be that of providing a pharmaceutical preparation that also does not require additives.

The problem is solved by providing a pharmaceutical

preparation containing the antigen described above in combination with an OmpA protein.

This solution cannot be derived from any prior art document or from any combination of a plurality of such documents. Therefore, **independent claims 1 and 19** are **considered to be inventive** (PCT Article 33(3)).

2.2 **The same applies to dependent claims 2-16 and 18-24.**

3. There are no uniform criteria in the PCT for determining whether claims 1-16 are industrially applicable. Patentability may also be dependent on the way in which the claims are worded. Therefore, the European Patent Office does not consider the subject matter of use claims relating to the medical use of a compound to be industrially applicable. However, claims relating to a known compound, for a first medical use, will be accepted, as will claims relating to the use of such a compound for producing a drug with a view to a novel medical treatment.

**VII. Certain defects in the international application**

The following defects in the form or contents of the international application have been noted:

Contrary to the requirement of PCT Rule 5.1(a)(ii), the relevant prior art disclosed in document D3 has not been indicated in the description, nor has this document been cited.

**VIII. Certain observations on the international application**

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Since the expression "a fragment thereof" used in claims 1-4, 8, 10, 12 and 21 as well as the term "nucleic construct" used in claims 13 and 19 have a relative meaning, they do not have a well established and recognised meaning. It follows that they cast doubt on the meaning of the technical features to which they refer, and the subject matter of said claims has not been clearly defined (PCT Article 6).

2. Claim 17 is unclear (PCT Article 6) because it has not been defined in terms of a technical feature.

3. The use of the expression "fragment with at least 5 amino acids" in claims 6, 18 and 19 does not have a specific meaning and renders the claims unclear (PCT Article 6). Said expression also covers substances that are not capable of solving the technical problem addressed by the present application.